



REMARKS/ARGUMENTS

Claim Status/Support For Claim Amendment

Claim 1 has been amended. Claims 2-35 have been cancelled. Claims 36-43 have been added. Applicants hereby authorize Deposit Account No. 50-1803 to be charged in the amount of \$156.00 for the examination of eight new claims and two extra new independent claims over the number of total claims previously paid for. Claims 1 and 36-43 are pending in the instant application.

The above additions to the claims find basis in the original disclosure at page 12, lines 2-12; page 16, line 2 to page 18, line 10 and page 27, lines 17-23 to page 28, lines 1-2. The method of claims 36 and 39 is described in detail at pages 20-28. Page 28, line 11 to page 29, line 7 refers to the use of various types of samples and their measurement. Page 28, line 20 to page 29, line 7 refers to immunoassay techniques which are well known in the art and provides a citation for an article by Takahashi which is incorporated into the instant specification by reference at page 33, lines 3-8. The Takahashi article describes the standard use of obtaining more than one sample and at different time periods. Page 29, line 8 to page 31, line 5 describes the use of monoclonal antibodies and their production. Page 31, lines 6-8 refer to the use of polyclonal antibodies

produced in an animal host. It is clear from these specific recitations and from the description of methods utilized that the methods and types of kits were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

Drawings

The Official Draftsperson objected to the drawings (filed on November 4, 2002) under 37 CFR 1.84(l) as indicated on the PTO-948 form attached to the Office Action mailed on November 25, 2002. Applicants have reviewed the drawings and submit herewith corrected formal drawings.

Sequence Compliance

In the Office Action mailed on November 25, 2002, the Examiner objected to the disclosure because the application fails to comply with the sequence requirements of 37 CFR 1.821-1.825. Applicants filed a Supplemental Preliminary Amendment on March 19, 2002 in order to correct sequence informalities. In a telephone conference, the Examiner acknowledged that this amendment had been received and entered. However, Applicants have now reviewed the entire specification again, including the figures, for sequence disclosures and discovered that sequence identifiers were missing from the figures. Additionally, Applicants noted that amino acid residues 1 and 12 necessary for

protein purification were missing from SEQ ID NO:1. Applicants herein amend the specification to add sequence identifiers to the sequences disclosed in the figures. Additionally, applicants herein provide a diskette containing a substitute Sequence Listing in electronic computer readable form to replace the previously submitted copy (filed on March 19, 2002) which adds amino acid residues 1 and 12 to SEQ ID NO:1. Applicants also provide a substitute paper copy of the Sequence Listing as contained on the diskette filed herewith. The computer readable form of the substitute Sequence Listing is identical to the paper copy of the substitute Sequence Listing. The subject matter of the substitute Sequence Listing filed herewith was contained in the application as originally filed (see Figure 1 for sequences including protein purification residues 1 and 12). No new matter has been added.

Declaration Under 37 CFR 1.132

A declaration under 37 CFR 1.132 is filed concurrently herewith in order to provide evidence of the absence of the biopolymer marker (amino acid residues 2-11 of SEQ ID NO:1) weighing 1211 daltons in normal human sera.



Conclusion

Now that applicants have fully responded to the Office action mailed on November 25, 2002, an examination on the merits is respectfully requested.

Respectfully submitted,

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